



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Sullivan
9/19/89

In re Application of:
EDWARD A. BOYSE et al.
Application No. 07/119,746
Filed: November 12, 1987

) Group Art Unit: 182
)
) Examiner: Sam Rosen

) RECEIVED GROUP 180

) For: ISOLATION AND PRESERVATION
) OF FETAL AND NEONATAL
) HEMATOPOIETIC STEM AND
) PROGENITOR CELLS OF THE
) BLOOD

) SEP 15 1989

) PENNIE & EDMONDS
) 1155 Avenue of the Americas
) New York, New York 10036

) Attorney Docket No. 6287-003
)

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT
UNDER 37 C.F.R. § 1.56

Honorable Commissioner of Patents and Trademarks
Washington, D.C. 20231

S I R:

In accordance with the continuing duty of disclosure imposed by 37 C.F.R. § 1.56, Applicants hereby direct the Examiner's attention to the following references, copies of which are being submitted herewith.

Each of the references listed below is discussed briefly infra. The letters in brackets after each reference correspond to the references listed on attached revised form PTO-1449 entitled List of References Cited by Applicants, and continue from the last reference of the Information Disclosure Statement filed on February 22, 1989 for the above-identified application.

CERTIFICATE UNDER 37 CFR 1.8(a)

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner of Patents and Trademarks, Washington, D.C. 20231, on 9-5-89 (Date of Deposit)

9-5-89
(Date of Signature)

Adriane Gentler 30,605
(Reg. No.)

List of References

A. Hematopoietic Reconstitution

1. Gluckman et al., 1980, Brit. J. Haematol. 45:557-564. [CJ]
2. Abrams et al., 1983, J. Cell. Biochem. Suppl. 7A:53 (Abstr. 0128). [CK]
3. Raghavachar et al., 1983, J. Cell. Biochem. Suppl. 7A:78 (Abstr. 0198). [CL]
4. Champlin et al., 1983, J. Cell Biochem. Suppl. 7A:78 (Abstr. 0200). [CM]
5. Gluckman et al., 1983, Brit. J. Haematol. 54:431-440. [CN]
6. Gluckman et al., 1984, Sem. Hematol. 21(1):20-26. [CO]
7. Gluckman et al., 1985, The Cancer Bulletin 37(5):238-242. [CP]

The 1980 reference by Gluckman et al. describes the use of bone marrow transplantation for treatment of patients with Fanconi anemia.

The 1983 reference by Abrams et al. discloses that, in a canine model, peripheral blood mononuclear cells collected after cyclophosphamide-induced expansion of CFU-GM progenitor cells have increased reconstitutive potency, and transplantation of peripheral blood mononuclear cells combined with bone marrow samples resulted in hematopoietic reconstitution.

The 1983 reference by Raghavacher et al. describes the hematopoietic reconstitution of total-body irradiated dogs by use of either cryopreserved autologous peripheral blood or cryopreserved autologous bone marrow.

The 1983 reference by Champlin et al. describes the use of fetal liver cell transplantation in dogs to effect hematopoietic reconstitution of total-body irradiated dogs.

The 1983 reference by Gluckman et al. describes a study of the appropriate conditioning regimen for use with bone marrow transplantation for treatment of patients with Fanconi anemia.

The 1984 reference by Gluckman et al. reviews the use of bone marrow transplantation for treatment of patients with Fanconi anemia.

The 1985 reference by Gluckman et al. describes the results of using bone marrow transplantation for treatment of patients with Fanconi anemia.

B. References Cited in the International Search Report for Corresponding PCT International Application No. PCT/US88/04044

8. U.S. Patent No. 3,758,382, filed July 26, 1968. [CQ]
9. U.S. Patent No. 4,004,975, filed December 30, 1975. [CR]
10. U.S. Patent No. 4,396,601, filed March 26, 1980. [CS]
11. U.S. Patent No. 4,224,404, filed December 14, 1977. [CT]

U.S. Patent No. 3,758,382 discloses a method of cryopreserving blood by use of hydroxyethyl or hydropropyl starch as a cryoprotective agent.

U.S. Patent No. 4,004,975 discloses a method of isolating and cryopreserving white blood cells from whole human blood.

U.S. Patent No. 4,396,601 describes methods and compositions for gene therapy by transfer and expression of exogenous genes in mammals. Host cells suitable for use as transfer vehicles for the exogenous genetic materials are disclosed to include bone marrow, in particular, stem cells.

U.S. Patent No. 4,224,404 discloses methods for the production of gamma globulins and immune nucleic acids, specific to a given antigen, by culturing an inducible

lymphoid cell line in the presence of specific immune nucleic acids or dialysates. Cell line LDV/7 is described, and reported to possibly contain lymphoblastoid and/or stem cells.

C. Human Neonatal Umbilical Cord Blood

12. Ende, M. 1966, Pac. Med. & Surg.
74:80-82. [CU]
13. Ende, M. and Ende, N., 1972,
Va. Med. Monthly 99:276-280. [CV]

The 1966 reference by Ende describes the administration of human umbilical cord blood to a patient with lymphangiosarcoma. The author states that the administration of cord blood was undertaken because such blood may contain factors which inhibit neoplasms. Cord blood from 17 different deliveries was administered over a period of almost one month, from which the patient "seemed to derive some temporary benefit." There was no cryopreservation of cord blood prior to transfusion.

The 1972 reference by Ende and Ende describes an attempted hematopoietic reconstitution of a patient with acute lymphoblastic leukemia, by the transfusion of a total of eight human umbilical cord blood samples from different donors, over a period of 17 days. There was no cryopreservation of cord blood prior to transfusion. Only a brief, temporary change in the patient's blood cell phenotype was observed.

Identification of the above-listed references is not to be construed an admission of Applicants or Attorneys for applicants that such references are available as "prior art" against the subject application. Consequently, Applicants respectfully decline to use form PTO-1449, since this form identifies all of the references cited therein as "Prior Art." As an alternative, Applicants

submit herewith several pages of a "revised form PTO Form 1449" entitled "List of References cited" instead of "List of Prior Art Cited."

Applicants respectfully request that the Examiner review the foregoing references and that the references be made of record in the file history of the application.

Respectfully submitted,

PENNIE & EDMONDS
Attorneys for applicants

By: *S. Leslie Misrock* */s/ Adriane Cantler*
S. Leslie Misrock (Reg. No. 18872) *Reg. No. 32,605*

Dated: 9-5-89
(212) 790-9090